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This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

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INVENTOR(S)		
Given Name (first and middle [if any])	Family Name or Surname	Residence (City and either State or Foreign Country)
Dirk	Boecker	Palo Alto, California
Dominique M.	Freeman	La Honda, California
Don	Alden	Sunnyvale, California

☐ *Additional inventors are being named on the _____ separately numbered sheets attached hereto*

TITLE OF THE INVENTION (500 characters max)

METHOD AND APPARATUS FOR A POINT OF CARE DEVICE

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ENCLOSED APPLICATION PARTS (check all that apply)

☑ Specification *Number of Pages* 11
☑ Drawing(s) *Number of Sheets* 2
☐ Application Data Sheet. See 37 CFR 1.76
☐ CD(s), Number
☑ Other (specify) **Application cover sheet; return postcard**

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☒ No.
☐ Yes, the name of the U.S. Government agency and the Government contract number are: _____

Respectfully submitted,

SIGNATURE _____ Date **06/13/2003**

TYPED or PRINTED NAME **Hao Y. Tung (Reg. No. 43,209)** REGISTRATION NO. *(if appropriate)* **43,209**

TELEPHONE **(650) 324-7000** Docket Number: **38187-2654**

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Attorney Docket No.: 38187-2654

PROVISIONAL PATENT APPLICATION
METHOD AND APPARATUS FOR A POINT OF CARE DEVICE

Inventor(s):

DOMINIQUE M. FREEMAN, a citizen of the United Kingdom
residing at 4545 La Honda Road
La Honda, California 94020

DIRK BOECKER, a citizen of Germany
residing at 1652 Castilleja Avenue
Palo Alto, California 94306

DON ALDEN, a citizen of the United States
residing at 1312 Nelson Way
Sunnyvale, California 94087

Assignee:

Pelikan Technologies, Inc.
1072 East Meadow Circle
Palo Alto, California 94303

Status: Small Entity

HELLER EHRMAN WHITE & MCAULIFFE LLP
275 Middlefield Road
Menlo Park, California 94025-3506
(650) 324-7000

PATENT

Attorney Docket No.: 38187-2654

METHOD AND APPARATUS FOR A POINT OF CARE DEVICE

BACKGROUND OF THE INVENTION

A. TECHNICAL FIELD

The technical field relates to using fluorescence or fluorescence lifetime decay of oxygen sensors to measure multiple parameters simultaneously such as pH, blood gases, electrolytes, immunoassay and hematology in a handheld miniaturized format using inexpensive electronics for illumination, detection, lancet actuation and data communication. Alternatively, electrochemical tests suitable for point of care testing can be employed.

B. RELATED ART

POC (point of care) testing is attractive because it rapidly delivers results to the medical practitioner and enables faster consultation with the patient enabling the practitioner to commence treatment sooner, perhaps leading towards improved patient outcomes. Relevant art includes the use of screening and monitoring diagnostics for early intervention, such as cardiac markers for early detection of angina, coronary artery occlusion and ruling out chest pain (triage). Examples of POC tests include blood chemistry such as glucose, lactate, electrolytes, as well as hematology, immuno-diagnostics, drugs of abuse, serum cholesterol, fecal occult blood test ("FOBT"), pregnancy, and ovulation. Examples of electrochemical Point of Care devices, which are hand, held are given by the i-STAT where electrochemical tests are carried out on a few drops of blood. Based on Microfabricated thin film electrodes, common tests include creatinine, or glucose on single cartridges, or combined tests such as sodium, potassium, hematocrit and hemoglobin on a single cartridge. Tests are combined on cartridges depending on the application e.g. blood gas panel etc. One disadvantage to this deployment of tests on panel specific cartridges is that in some cases several cartridges may be used to obtain complete POC information from the patient.

Current POC devices such as the i-STAT do not provide an integrated solution for patient self-testing for sample acquisition, testing, analysis and connectivity to remote

centralized healthcare. Accordingly it is the object of this invention to provide a portable, highly integrated, multi-parameter measurement instrument where sampling is integrated with measurement processes from 1 μL of blood or less. Integration will allow the broad deployment of tests for a single sample acquisition step. This fully integrated blood sampling and measurement technology platform has been established for glucose spot monitoring, (WO 02/1000254 Lancet launching device integrated on to a blood sampling cartridge) in a multi-test format (100+ tests) employing an electronic blood-sampling device (WO 02/100460 Electric lancet actuator, WO 02/100251 Self optimizing lancing device) embedded within a glucose measurement instrument and a data management system (WO 02/101359 Integrated blood sampling and analysis system with multi use sampling module). Optical measurement of analytes provides the potential to monitor important clinical analytes for Point of Care applications. Fluorescent amplitude or lifetime decay optical measurements of glucose can be made with low-cost, low-power consumption components that are compatible with handheld instrumentation. These components include LED's, plastic optical elements, and CMOS or photodiode light detectors. The opportunity exists to carry out multiple measurements on the same sample to obtain more precise results or to analyze for components other than glucose (US. 6,379,969 Optical sensor for sensing multiple analytes)

These POC still use a body fluid sample. Obtaining such a sample using conventional lancing device can be painful. Early methods of lancing included piercing or slicing the skin with a needle or razor. Current methods utilize lancing devices that contain a multitude of spring, cam and mass actuators to drive the lancet. These include cantilever springs, diaphragms, coil springs, as well as gravity plumbs used to drive the lancet. The device may be held against the skin and mechanically triggered to ballistically launch the lancet. Unfortunately, the pain associated with each lancing event using known technology discourages patients from testing. In addition to vibratory stimulation of the skin as the driver impacts the end of a launcher stop, known spring based devices have the possibility of firing lancets that harmonically oscillate against the patient tissue, causing multiple strikes due to recoil. This recoil and multiple strikes of the lancet is one major impediment to patient compliance with a structured glucose monitoring regime.

Another impediment to uncomfortable patient experience of giving a blood sample is the lack of spontaneous blood flow generated by known lancing technology. In addition to the pain as discussed above, a patient may need more than one lancing event to obtain a blood sample since spontaneous blood generation is unreliable using known lancing technology. Thus the pain is multiplied by the number of attempts required by a patient to successfully generate spontaneous blood flow. Different skin thickness may yield different results in terms of pain perception, blood yield and success rate of obtaining blood between different users of the lancing device. Known devices poorly account for these skin thickness variations.

SUMMARY OF THE INVENTION

The present invention provides solutions for at least some of the drawbacks discussed above. Specifically, some embodiments of the present invention provide an improved body fluid sampling device. The device may be used to perform a plurality of analyte tests on a single sample. At least some of these and other objectives described herein will be met by embodiments of the present invention.

In one embodiment, the present invention provides a multiple sensor and multiple lancet solution to measure analyte levels in the body. The invention may use a high-density sensor design of electrochemical or optical origin using multiple sensors to measure an analyte in a body fluid. It may use lancets of smaller size than known lancets. The device may be used for multiple lancing events without having to remove a disposable from the device.

A further understanding of the nature and advantages of the invention will become apparent by reference to the remaining portions of the specification and drawings.

DESCRIPTION OF THE SPECIFIC EMBODIMENTS

The present invention provides a solution for body fluid sampling. Specifically, some embodiments of the present invention provides a method for improving spontaneous blood generation. Some embodiments of the present invention provide an improved body fluid sampling device. For some embodiments of these penetrating member drivers, the invention relates to a new contact point algorithm that is run

immediately before the actual lance event. At least some of these and other objectives described herein will be met by embodiments of the present invention.

It is to be understood that both the foregoing general description and the following detailed description are exemplary and explanatory only and are not restrictive of the invention, as claimed. It may be noted that, as used in the specification and the appended claims, the singular forms "a", "an" and "the" include plural referents unless the context clearly dictates otherwise. Thus, for example, reference to "a material" may include mixtures of materials, reference to "a chamber" may include multiple chambers, and the like. References cited herein are hereby incorporated by reference in their entirety, except to the extent that they conflict with teachings explicitly set forth in this specification.

In this specification and in the claims which follow, reference will be made to a number of terms which shall be defined to have the following meanings:

"Optional" or "optionally" means that the subsequently described circumstance may or may not occur, so that the description includes instances where the circumstance occurs and instances where it does not. For example, if a device optionally contains a feature for analyzing a blood sample, this means that the analysis feature may or may not be present, and, thus, the description includes structures wherein a device possesses the analysis feature and structures wherein the analysis feature is not present.

Chemical sensor formulations have been developed that are capable of conducting numerous different chemical analyses on small samples, so that the maximum number of medical tests can be made using the minimum amount of sample. Volume of less than 100 nL are possible. These blood chemistry tests include small molecules such as glucose and lactate, blood gasses (including pO_2, pCO_2), blood pH, ions (Na^+, Ca^{++}, K^+), and hematology, hematocrit and coagulation and hemoglobin factors, as well as immuno-diagnostics, and DNA testing. Parallel testing can be performed on the sensing cartridge using fluorescence-based detection using oxygen sensors so that a wide variety of tests can be performed using optical sensors for several species that can be interrogated with one illumination source and read with one detector (Wolfbeis O. Sensors and Actuators B 51 (1998) 17-24). Analysis of multiple analytes from a fluid of unknown composition has been described (US 6,379,969 Mauze et al). Analysis of a plurality of metabolites in a hand held diagnostic device using a single cartridge requiring 1-3 μL of blood has also been described (US2003/0073931 Universal Diagnostic platform, US2003/0073089

Companion cartridge for disposable diagnostic testing). There is a need for a plurality of POC tests on a single cartridge such that sequential tests may be performed in an integrated fashion without changing the test cartridge. Each cartridge can contain a lancet sensor combination in a radial disk format, interrogated and read by a single illumination/detection device. Alternatively a series of tests can be measured electrochemically and reported. Only those tests, which are required at the time, the sample is taken need to be reported, though all tests are carried out. This avoids having the change cartridges for a specific combination or panel since bundled tests with menu option has not been commercially successful as several cartridges for given disease state are required. Test combinations may include a plurality of tests for a single lancet/sensor combination repeated up to 100 times. The nominal test panel would include blood gasses, electrolytes, metabolites, immunoassay and coagulation as a first choice. Cell counting and hematology are complex and may require almost 75% more space in the sensor area to complete. This may be accomplished by using the underside of the disk and a second layer if more surface area is required.

The invention is comprised of an electronic lancet driver to penetrate tissue, a single disposable cartridge containing lancet/sensor pairs arranged on a radial disk of about 6 cm in diameter. Lancets are coupled to the electronic actuator, which can actuate the lancets radially outward from the cartridge to penetrate tissue. Optical or electrochemical analyte sensors are coupled to the cartridge (Figure 1), and positioned on the cartridge to receive blood from the wound created by the lancet. Capillary forces draw the blood sample, which flows from the wound to the surface of the skin, through an opening and then to the sensor chamber situated, on the support disc (Figure 2 a and b). Once blood fills the sensor, analytical testing can be performed on the sample. Results are read optically via transparent windows aligned with optical sensors, or electrochemically from electrodes in contact with the biosensor chemistry.

Chemical tests are started simultaneously by having the blood fill a prefill chamber. It is microfluidically designed so that when enough sample has arrived to fill all the sensors it is primed to empty and fill the sensor chemistry zones instantaneously. A blister is included. The cartridge can be manufactured under pressure. When the blister is broken (either by the indexing mechanism or another method) the pressure is released and calibration and or washing fluid can be released throughout the test area prior to the

arrival of blood sample to the test region so that equilibration can take place if required. A vent may also be included to prevent overfill of the cartridge if too much sample is delivered. Additionally and fill indicator may be present to indicate adequate sample fill of the sample chamber.

It should be understood that embodiments of the present invention may provide at least some of the following advantages. All of the advantages miniaturized, disposable, biohazard etc, as described in commonly assigned copending U.S. Patent Application Ser. No. _____ (Attorney Docket No. 38187-2551, 38187-2609, and 38187-2662). The device may have handheld, two way communication, data management (as per US 2003/0073931 A1 Universal diagnostic platform). The device may have integrated sampling/POC testing device for one step sample to read. The device may have blood volume requirement less than 1 microL. The device may have many tests on single sensor/penetrating member combination. Each segment may have the same test or the cartridge can be divided into regions with a plurality of specific tests. All tests run, subset reported, cost of test only for tests required. Analyte sensors may be electrochemical or optical (or any combination of both or other sensor types). The device may include companion cartridge for more complex less common tests, only used if required. The underside of a cartridge as described in 38187-2662 used for tests requiring larger surface area e.g. washing steps in hematology or cell counting. All tests may start simultaneously by means of an upstream fixed volume chamber which empties instantaneously when full. The device may have vents, seals, fill detectors as described in 38187-2582. Cartridge vent system opens by piercing mechanism to allow on board calibration fluids to start flowing into relevant fluidic structures. The device may optically interrogate from bottom as in F1 optical disclosure. Array detection may be used as in 38187-2609.

While the invention has been described and illustrated with reference to certain particular embodiments thereof, those skilled in the art will appreciate that various adaptations, changes, modifications, substitutions, deletions, or additions of procedures and protocols may be made without departing from the spirit and scope of the invention. For example, with any of the above embodiments, the location of the penetrating member drive device may be varied, relative to the penetrating members or the cartridge. With any of the above embodiments, the penetrating member tips may be uncovered during actuation (i.e. penetrating members do not pierce the penetrating member enclosure or

protective foil during launch). With any of the above embodiments, the penetrating members may be a bare penetrating member during launch. With any of the above embodiments, the penetrating members may be bare penetrating members prior to launch as this may allow for significantly tighter densities of penetrating members. In some embodiments, the penetrating members may be bent, curved, textured, shaped, or otherwise treated at a proximal end or area to facilitate handling by an actuator. The penetrating member may be configured to have a notch or groove to facilitate coupling to a gripper. The notch or groove may be formed along an elongate portion of the penetrating member. With any of the above embodiments, the cavity may be on the bottom or the top of the cartridge, with the gripper on the other side. In some embodiments, analyte detecting members may be printed on the top, bottom, or side of the cavities. The front end of the cartridge maybe in contact with a user during lancing. The same driver may be used for advancing and retraction of the penetrating member. The penetrating member may have a diameters and length suitable for obtaining the blood volumes described herein. The penetrating member driver may also be in substantially the same plane as the cartridge. The driver may use a through hole or other opening to engage a proximal end of a penetrating member to actuate the penetrating member along a path into and out of the tissue. The embodiments herein are adapted for use with lancing devices described in U.S. Patent Applications Ser. No. _____ Attorney Docket No. 38187-2551US and 38187-2606.

Expected variations or differences in the results are contemplated in accordance with the objects and practices of the present invention. It is intended, therefore, that the invention be defined by the scope of the claims which follow and that such claims be interpreted as broadly as is reasonable.

WHAT IS CLAIMED IS:

1. A body fluid sampling device for use with a cartridge containing a plurality of penetrating members comprising:

a penetrating member driver for moving an active one of said penetrating members from a first position outward to penetrate tissue;

a penetrating member coupler attached to said driver;

a cutting device that simultaneously cuts a sterility barrier on said cartridge while moving along a path that rotates the cartridge about its center to align the newly opened cavity in the cartridge with the penetrating member coupler.

2. The device of claim 1 wherein the penetrating member driver is coupled to a position sensor, said sensor used to detect a position of the active one of said penetrating member.

3. A body fluid sampling device for use with a cartridge containing a plurality of penetrating members comprising:

a penetrating member driver for moving an active one of said penetrating members from a first position outward to penetrate tissue;

a penetrating member coupler attached to said driver;

at least one of the following features may be included:

- Handheld, two way communication, data management (as per US 2003/0073931 A1 Universal diagnostic platform)
- Integrated sampling/POC testing device for one step sample to read
- Blood volume requirement less than 1 uL
- Many tests on single sensor/lancet combination
- Each segment has the same test or the cartridge can be divided into regions with a plurality of specific tests.
- All tests run, subset reported, cost of test only for tests required
- Electrochemical or optical (or both)
- Companion cartridge for more complex less common tests, only used if required.
- Underside of Saturn cartridge used for tests requiring larger surface area e.g. washing steps in hematology or cell counting.

- All tests start simultaneously by means of an upstream fixed volume chamber which empties instantaneously when full
- Vents, seals, fill detectors
- Cartridge vent system opens by piercing mechanism to allow on board calibration fluids to start flowing into relevant fluidic structures.
- Optically interrogate from bottom as in F1 optical disclosure and
- Array detection

ABSTRACT

A plurality of POC tests on a single cartridge is provided such that sequential tests may be performed in an integrated fashion without changing the test cartridge. Each cartridge can contain a lancet sensor combination in a radial disk format, interrogated and read by a single illumination/detection device. Alternatively a series of tests can be measured electrochemically and reported. Only those tests, which are required at the time, the sample is taken need to be reported, though all tests are carried out.

Figure 1 (a) Optical sensor for multiple analyte testing in a single lancet/sensor combination.

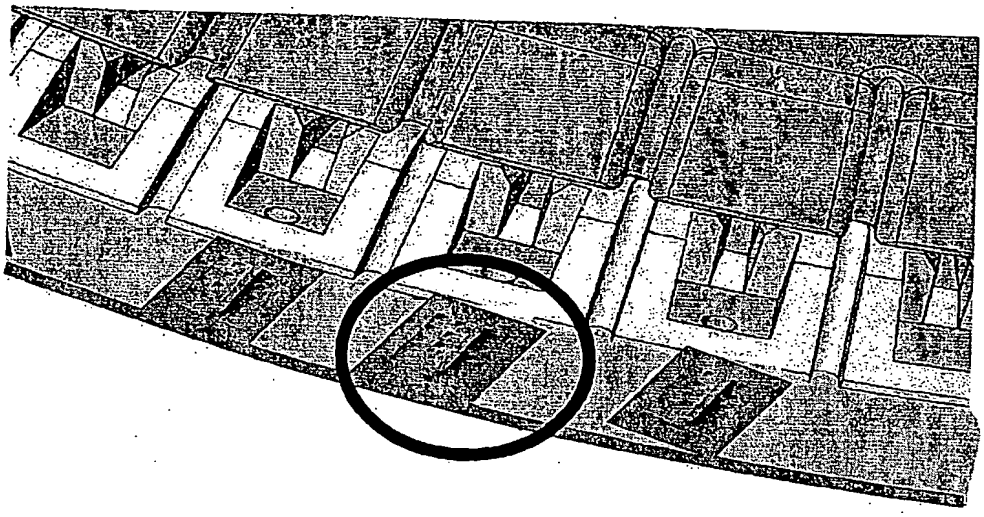


Figure 1 (b) Electrochemical sensor showing lancet orientation with respect to electrochemical sensor for multiple analyte testing in a point of care setting.

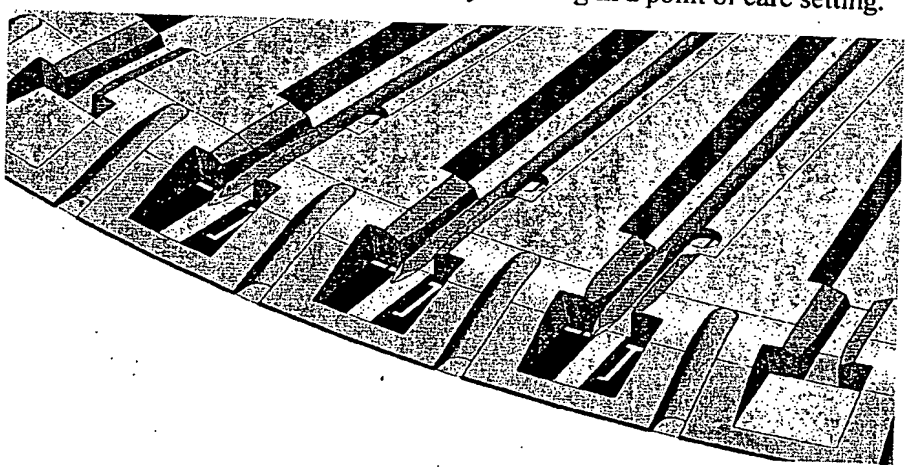


Figure 2

(a) Section of lancet/sensor pair

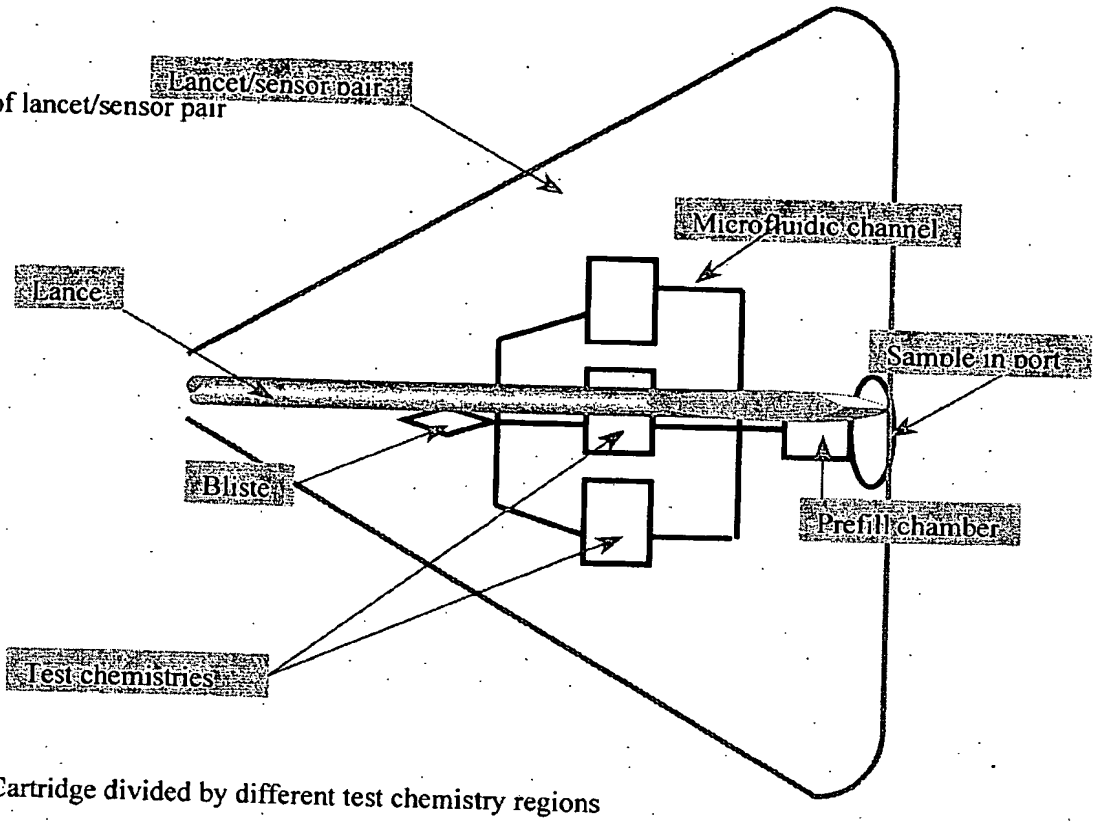
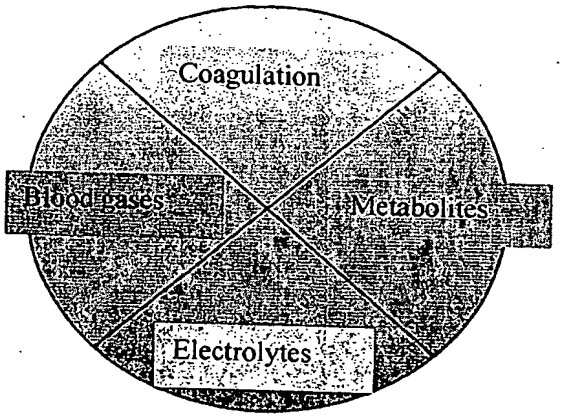


Figure 2 (b) Cartridge divided by different test chemistry regions



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